

(19) World Intellectual Property
Organization
International Bureau



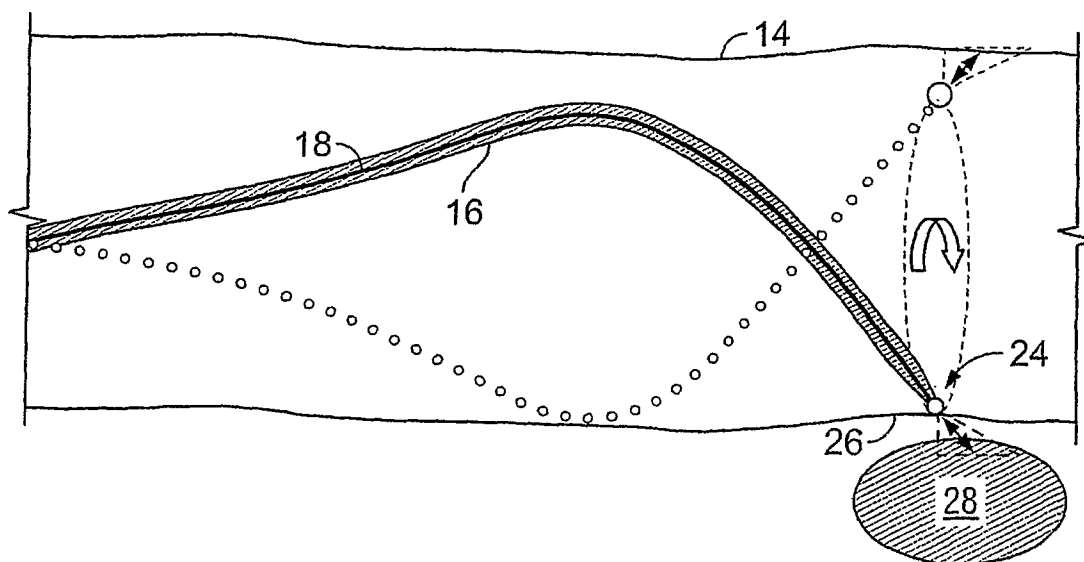
(43) International Publication Date
6 January 2005 (06.01.2005)

PCT

(10) International Publication Number
WO 2005/000115 A1

- (51) International Patent Classification⁷: **A61B 5/00**
- (21) International Application Number:
PCT/US2004/019883
- (22) International Filing Date: 21 June 2004 (21.06.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
10/602,345 23 June 2003 (23.06.2003) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 10/602,345 (CIP)
Filed on 23 June 2003 (23.06.2003)
- (71) Applicant (for all designated States except US): **INFRAREDIX, INC.** [US/US]; 125 Cambridge Park Drive, Cambridge, MA 02140 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **ZULUAGA, Andres** [US/US]; 130 Bowdoin Street, Apt. 1808, Boston, MA 02108 (US). **FURNISH, Simon** [US/US]; 30 St. Mark's Place #2D, New York, NY 10003 (US). **CAPLAN, Jay** [US/US]; 34 Clark Street, Belmont, MA 02478 (US).
- (74) Agent: **FASSE, Peter, J.**; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110-2804 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTRALUMINAL SPECTROSCOPE WITH WALL-CONTACTING PROBE



(57) Abstract: The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)). An atraumatic light-coupler (24) at the distal end of the probe (16) rests on a contact area (26) on the arterial wall (14) which directs light from fiber (18) to the arterial wall (14) illuminating the structures (28) behind the wall (14). These structures (28) scatter some of the light back to the contact area (26), where it re-emerges through the arterial wall (14). The atraumatic light-coupler (24) collects this re-emergent light and directs it into the fiber (18).

WO 2005/000115 A1

INTRALUMINAL SPECTROSCOPE WITH WALL-CONTACTING PROBE

FIELD OF INVENTION

The invention relates to spectroscopy, and in particular, to spectrometers for detecting vulnerable plaques within a wall of a blood vessel.

BACKGROUND

Atherosclerosis is a vascular disease characterized by a modification of the walls of blood-carrying vessels. Such modifications, when they occur at discrete locations or pockets of diseased vessels, are referred to as plaques. Certain types of plaques are associated with acute events such as stroke or myocardial infarction. These plaques are referred to as "vulnerable plaques." A vulnerable plaque typically includes a lipid-containing pool of necrotic debris separated from the blood by a thin fibrous cap. In response to elevated intraluminal pressure or vasospasm, the fibrous cap can become disrupted, exposing the contents of the plaque to the flowing blood. The resulting thrombus can lead to ischemia or to the shedding of emboli.

One method of locating vulnerable plaque is to peer through the arterial wall with infrared light. To do so, one inserts a catheter through the lumen of the artery. The catheter includes a delivery fiber for illuminating a spot on the arterial wall with infrared light. Various particles in the blood, as well as the arterial wall itself, scatter or reflect much of this light. A small portion of the light, however, penetrates the arterial wall, scatters off structures deep within the wall. Some of this deeply-scattered light re-enters the lumen. This re-entrant light can be collected by a collection fiber within the catheter and subjected to spectroscopic analysis.

In an effort to avoid recovering light scattered from the blood and from the wall surface, the delivery fiber is displaced from the collection fiber. The diameter of the catheter must therefore be large enough to accommodate the two fibers and the gap that separates them.

SUMMARY

The invention is based on the recognition that by collecting scattered light directly from an intraluminal wall, one avoids scattering that results from propagation of light through blood. As a result, it is no longer necessary to provide separate collection and delivery fibers. Instead, only a single fiber is necessary.

In one aspect, the invention includes an apparatus for detecting vulnerable plaque within a lumen defined by an intraluminal wall. The apparatus includes a probe having one or more optical fiber extending therethrough, and an atraumatic coupler in communication with the optical fiber(s). The coupler is configured to atraumatically contact the intraluminal wall. The apparatus also includes a light source in optical communication with the fiber for illuminating the wall; and a detector in optical communication with the fiber for detecting light from within the wall.

In one embodiment, the probe includes a jacket enclosing the fiber. The jacket can be a coil-wire wound into a coil-wire jacket, with or without a variable diameter coil wire.

In other embodiments, the probe resiliently assumes a preferred shape. Examples of preferred shapes include a bow, an arc, a catenary, or a portion thereof.

The atraumatic coupler can be on the distal end of the probe. Embodiments of this type include those in which the atraumatic coupler is a lens attached to the distal tip of the optical fiber. In some embodiments, the lens has a focal length that limits the divergence angle of a beam mode-matched to the optical fiber, for example, to an angle less than about 20 degrees. In some embodiments, the lens includes a collimating lens.

In some embodiments the atraumatic coupler includes a divergence limiter attached to the distal tip of the optical fiber. In one embodiment, the divergence limiter includes a thermally-expanded fiber core section of the optical fiber.

Additional embodiments include those in which the atraumatic coupler is integral with the optical fiber, as for example where a distal tip of the optical fiber forms part of

the atraumatic coupler. In some embodiments, the optical fiber has an acceptance angle smaller than about 20 degrees.

The atraumatic coupler can also be along a side of the probe. Examples of such couplers include those having a window along a side of the probe, and a beam re-director providing optical communication between the window and a distal tip of the fiber. Other examples include those in which a distal face of the optical fiber provides optical communication with the window.

The invention optionally includes a cannula through which the probe passes. The cannula can include walls forming a channel conformal with the cannula through which the probe passes. In these embodiments, the probe can be steered toward the wall by providing tapered or flared distal end having an opening facing toward or away from a longitudinal axis of the cannula.

Other embodiments include those having a hub to which a distal end of the probe is attached, and those in which a cannula is provided for the hub and probe to pass through. In these embodiments, the probe can be one that resiliently assumes a bow shape for contacting the intraluminal wall at a point of inflection thereof. A coupler can then be placed at the point of inflection.

In another aspect, the invention includes an apparatus having a cannula and a plurality of probes extending through the cannula. Each probe has an optical fiber extending therethrough, and an atraumatic coupler in communication with the optical fiber. The coupler is configured to atraumatically contact the intraluminal wall.

Some embodiments include a spacer ring attached to each of the probes for maintaining the positions of the probes relative to each other. Others include a hub attached to a distal end of each of the probes.

Another aspect of the invention is a method of detecting vulnerable plaque within an intraluminal wall. The method includes placing an atraumatic light coupler in contact with the intraluminal wall and passing light through the intraluminal wall by way of the atraumatic light coupler. Light from within the intraluminal wall is then recovered by

way of the atraumatic coupler. This light is then provided to a processor for analysis to identify the presence of a vulnerable plaque.

In some practices of the method, placing an atraumatic light coupler in contact with the intraluminal wall includes placing a distal end of a probe in contact with the intraluminal wall. In other practices of the invention, it is a side of the probe that is placed in contact with the intraluminal wall.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic diagram of a spectroscope for identifying vulnerable plaque.

FIG. 2 is a schematic view of a probe in contact with the arterial wall.

FIG. 3 is a cross-section of the probe of FIG. 2.

FIGS. 4A-J are exemplary atraumatic light-couplers for an optical fiber.

FIGS. 5A-F are schematic views of single-probe spectroscopes.

FIGS. 6A-F are schematic views of multi-probe spectroscopes.

FIG. 7A is a schematic view of a probe emerging from a cannula having a tapered distal end.

FIG. 7B is a schematic view of a probe emerging from a cannula having a flared distal end.

FIGS. 8A-8F are schematic views of multi-probe spectroscopes in which the atraumatic light-couplers are along the sides of the probes.

FIGS. 8G-K are schematic views of spectroscopes in which the probes are integrated into the cannula.

FIGS. 9A-D are views of exemplary atraumatic light-couplers for the probes in FIGS. 8A-H.

DETAILED DESCRIPTION

FIG. 1 shows a spectroscope **10** for identifying vulnerable plaque **12** in an arterial wall **14** of a patient. The spectroscope features a probe **16** to be inserted into a selected artery, e.g. a coronary artery, of the patient. An optical fiber **18** extends between a distal end and a proximal end of the probe **16**.

In a first embodiment, shown in FIGS. 2-3, an atraumatic light-coupler **24** at the distal end of the probe **16** rests on a contact area **26** on the arterial wall **14**. When disposed as shown in FIG. 2, the atraumatic light-coupler **24** directs light traveling axially on the fiber **18** to the contact area **26**. After leaving the atraumatic light-coupler **24**, this light crosses the arterial wall **14** and illuminates structures **28** behind the wall **14**. These structures **28** scatter some of the light back to the contact area **26**, where it re-emerges through the arterial wall **14**. The atraumatic light-coupler **24** collects this re-emergent light and directs it into the fiber **18**.

Along a proximal section of the probe **16**, as shown in FIG. 3, a rigid tube **38** encasing the fiber **18**, enables the probe **16** to be pushed through the artery. Along a central and distal section of the probe **16**, a coil wire **44** wound into a flexible coil-wire jacket **46** encases the fiber **18**.

The coil wire **44** has a constant diameter along the central section. Along the distal section of the probe **16**, the diameter of the coil wire **44** becomes progressively

smaller. As a result, the distal section of the probe **16** is more flexible than its central section. This enhanced flexibility enables the distal section to follow the contour of the wall **14** without exerting unnecessary force against it.

The atraumatic light-coupler **24** can be formed by attaching a lens assembly to a distal tip of the fiber **18**, as shown in FIGS. 4A, 4B, and 4E, or by attaching a rounded glass tip to an angled fiber, as shown in FIGS. 4F-G. Alternatively, the atraumatic light-coupler **24** can be made integral with the fiber **18** by smoothing any sharp edges at its distal tip, as shown in FIGS. 4C-D.

In either case, the atraumatic light-coupler **24** can include a spherical lens, as shown in FIG. 4A, or a hemispherical lens, as shown in FIG. 4B. The atraumatic light-coupler **24** can also include more than one lens element, as shown in FIG. 4E.

Alternatively, the atraumatic light-coupler **24** can be integral with the fiber **18**. For example, the distal tip of the fiber **18** can be formed into a plane having rounded edges and oriented at an angle relative to the plane of the fiber cross-section, as shown in FIG. 4D, or into a hemisphere, as shown in FIG. 4C.

Referring to FIGS. 4H-4J, in some embodiments, the atraumatic light-coupler **24** includes an attached or integral portion that acts as a beam divergence limiter **30**. The beam divergence limiter **30** limits the divergence half-angle θ of a beam **32** that is spatially mode-matched to the fiber **18** (e.g., a beam coupled into the fiber, out of the fiber, or both). For example, in FIG. 4I the beam divergence limiter **30** includes a lens **34** (e.g., a graded-index (GRIN) lens) positioned with respect to the end of the fiber **18**. The lens **34** has a focal length such that the mode-matched beam profile has a divergence half-angle θ that is less than about 10° (or near 0° if the lens **34** is a collimating lens, or less than 0° for a weakly converging beam).

In FIG. 4J the beam divergence limiter **30** includes an adiabatically tapered waveguide segment **36** (e.g., a thermally-expanded core (TEC) fiber segment) to couple a mode from the fiber **18** (e.g., a single mode fiber) to a low order mode of a large core section **38**. For a near Gaussian mode shape, the divergence half-angle θ of the beam for a

given wavelength of light varies inversely with core size. So the divergence angle 2θ of the beam 32 mode-matched to the large core section 38 is reduced.

Alternatively, the fiber 18 can be a low numerical aperture (NA) fiber (e.g., a single mode fiber having a small difference between the index of its core and the index of its cladding) that limits the divergence angle 2θ or "acceptance angle" without a separate beam divergence limiter 30, as in the configurations shown in FIGS. 4C-4D. For example, the fiber 18 can have a NA that limits the divergence angle 2θ to less than about 20° . Other elements can be used, such as a phase screen (or "Kinoform phase plate"), to limit beam divergence. A limited beam divergence using any of these methods is useful, for example, in using the atraumatic light-coupler 24 to perform optical coherence tomography (OCT).

Referring back to FIG. 1, one using the spectroscope 10 positions the atraumatic light-coupler 24 against the arterial wall 14 and engages a motor 49 coupled to the probe 16. The motor 49 rotates the probe 16 at a rate between approximately 1 revolution per second and 400 revolutions per second. This causes the atraumatic light-coupler 24 to trace a path around the inner circumference of the arterial wall 14. As it rotates, the atraumatic light coupler 24 redirects light placed on the fiber 18 by a light source 50, such as a near infrared light source, to the contact area 26. At the same time, the atraumatic light-coupler 24 collects light re-emerging from the contact area 26 and directs it into the fiber 18, which then guides it to a photo-detector 52.

The photo-detector 52 provides an electrical signal indicative of light intensity to an analog-to-digital ("A/D") converter 54. The A/D converter 54 converts this signal into digital data that can be analyzed by a processor 56 to identify the presence of vulnerable plaque hidden beneath the arterial wall 14.

In a second embodiment, shown in FIGS. 5A-C, a probe housing 59 extends through a cannula 60 parallel to, but radially displaced from a longitudinal axis thereof. A probe 16 is kept inside the probe housing 59 until it is ready to be deployed. Extending along the longitudinal axis of the cannula 60 is a guide-wire housing 61 forming a guide-wire lumen through which a guide-wire 63 extends.

The probe **16** can be an optical fiber made of glass or plastic, or a bundle of such fibers. In one embodiment, the probe includes a bundle of 25 optical fibers, each .005 millimeters in diameter. The fiber(s) can be exposed, coated with a protective biocompatible layer and/or a lubricious layer such as polytetrafluoroethylene ("PTFE"), or encased in a coil-wire jacket. The optional coating or jacket around the fiber(s) could be round, and hence bendable in all directions, or flat, so as to suppress bending in undesired directions.

The distal tip of the optical fiber **18** is capped by any of the atraumatic light-couplers **24** discussed above. When the distal end of the cannula **60** is just proximal to contact area **26**, the probe **16** is pushed distally so that its distal tip extends past the distal end of the cannula **60**. Alternatively, the probe **16** remains stationary while the cannula **60** is retracted, thereby exposing the probe **16**.

The probe **16** is pre-formed so that a natural bend urges it outward, away from the axis of the cannula **60**. As a result, when the probe **16** is extended out its housing **59** and beyond the distal end of the cannula **60**, this natural bend places the atraumatic light-coupler **24** of the fiber **18** in contact with the arterial wall **14** distal to the cannula **60**. The probe **16** is then rotated so that the atraumatic light-coupler **24** traces out a circular contact path along an inner circumference of the wall **14**, as shown in FIGS. 5A and 5C.

A variety of ways are known for pre-forming a probe **16**. For example, the probe **16** can be heated while in the desired shape. Or a coating over the fiber within the probe **16** can be applied and cured while the fiber is in the desired shape.

In a third embodiment, shown in FIGS. 5D-F, the cannula **60** has a proximal section **88** and a distal section **90** separated from each other by a circumferential gap **92**. A guide wall **94** forms a truncated cone extending distally from a truncated end joined to the guide-wire housing **59** to a base joined to the distal section **90** of the cannula **60**. The guide wall **94** thus serves to maintain the position of the proximal and distal sections **88**, **90** of the cannula **60** relative to each other while preserving the circumferential gap **92** all the way around the cannula **60**.

In use, the probe **16** is extended distally toward the guide wall **94**, which then guides the probe **16** out of the circumferential gap **62**. As was the case with the second embodiment (FIGS. 5A-C), the natural bend of the probe **16** urges the atraumatic tip **24** into contact with the arterial wall **14**. Once the probe's atraumatic tip **24** contacts the wall **14**, the probe **16** is rotated as shown in FIGS. 5D-F so that the atraumatic tip **24** sweeps a circumferential contact path on the arterial wall **14**.

In a fourth embodiment, shown in FIGS. 6A-C, several probes **16** of the type discussed above in connection with FIGS. 5A-F pass through the cannula **60** at the same time. Optional spacer rings **64** are attached to the probes **62** at one or more points along their distal sections. The spacer rings **64** can be silicon webbing, plastic, Nitinol, or any other biocompatible material.

When deployed, the spacer rings **64** are oriented so as to lie in a plane perpendicular to the longitudinal axis of the cannula **60**. The spacer rings **64** thus maintain the relative positions of the probes **16** during scanning of the wall **14**. A multi-probe embodiment as shown in FIGS. 6A-C enables most of the circumference of an arterial wall **14** to be examined without having to rotate the probes **16**.

In a fifth embodiment, shown in FIGS. 6D-F, the cannula **60** is as described in connection with the third embodiment (FIGS. 5D-F). The difference between this fifth embodiment and the third embodiment (FIGS. 5D-F) is that in the third embodiment, a single probe **16** extends through the circumferential gap **92**, whereas in this fifth embodiment, several probes **16** circumferentially offset from one another extend through the circumferential gap **92**. As a result, in the third embodiment, it is necessary to rotate the probe **16** to inspect the entire circumference of the arterial wall **14**, whereas in the fifth embodiment, one can inspect most of the arterial wall **14** circumference without having to rotate the probes **16** at all.

In a sixth embodiment, a cannula **60** has a tapered distal end **68**, as shown in FIG. 7A, or a flared distal end **70**, as shown in FIG. 7B. A channel **72** formed in the inner wall of the cannula **60** has a bend **74** proximal to an opening **76** at the distal end. This opening **76** defines a surface whose normal vector has both a radial component and an

longitudinal component.

One operating the embodiments of FIGS. 7A and 7B pushes the probe **16** through the channel **72**, which then guides it toward the opening **72**. As the probe **16** exits the channel **72**, it proceeds in the direction of the normal vector until its atraumatic light-coupler **24** contacts the arterial wall **14**. In this case, the probe **16** need not be pre-formed to have a preferred shape since the channel **72** guides the probe **16** in the correct direction for reaching the wall **14**.

In a seventh embodiment, shown in FIGS. 8A-B, a plurality of probes **16** passes through a cannula **60**. The distal ends of the probes **16** are attached to anchor points circumferentially distributed around a hub **78**. The hub **78** is coupled to a control wire **80** that enables it to be moved along the longitudinal axis of the cannula **60** to either deploy the probes **16** (FIG. 8A) or to retract the probes **16** (FIG. 8B). However, in other embodiments, the hub **78** remains stationary and it is the cannula **60** that is moved proximally and distally to either deploy or recover the probes **16**.

The probes **16** are pre-formed to bow outward as shown in FIG. 8A so as to contact the arterial wall **14** at an intermediate point between the hub **78** and the cannula **60**. Optional spacer rings **64**, like those discussed in connection with FIGS. 6A-C, are attached to the probes **16** at one or more points along their distal sections to maintain their relative positions. In this seventh embodiment, the atraumatic light-coupler **24** includes a side-window **82** located at the intermediate point. The side window **82** faces radially outward so that when the probe **16** is fully deployed, the side window **82** atraumatically contacts the arterial wall **14**.

An atraumatic light-coupler **24** for placement along the side of the probe **16** includes a right-angle reflector **84**, such as a prism or mirror, placed in optical communication between the fiber **18** and the side window **82**, as shown in FIG. 9B. Alternatively, an air gap **86** is placed in optical communication between the tip of an angle polished fiber **18** and the side-window **82**, as shown in FIG. 9A.

FIGS. 9C-9D shows additional examples of atraumatic light-couplers **24** for

placement along the side of the probe **16**. In these examples, the side window **82** is formed by a portion of the fiber's cladding that is thin enough to allow passage of light. The side window **82** can be left exposed, as shown in FIG. 9C, or a diffraction grating **85** can be placed in optical communication with the side window **82** to further control the direction of the beam, as shown in FIG. 9C.

When the hub **78** and the cannula **60** are drawn together, as shown in FIG. 8B, they can easily be guided to a location of interest. Once the hub **78** and cannula **60** reach a location of interest, one either advances the hub **78** or retracts the cannula **60**. In either case, the probes **16** are released from the confines of the cannula **60**, as shown in FIG. 8A. Once free of the radially restraining force applied by the cannula's inner wall, the probes **16** assume their natural shape, bowing outward, as shown in FIG. 8B, so that their respective side-windows **82** atraumatically contact the arterial wall **14**. The atraumatic light-couplers **24** guide light from the light source **50** through the side windows **82**. At the same time, the atraumatic light-couplers **24** recover re-emergent light from the wall **14** through the side windows **82** and pass it into the fibers **16**, which guide that light to the photo-detector **52**.

When the examination of the wall **14** is complete, the hub **78** and cannula **60** are brought back together, as shown in FIG. 8B, and the probes **16** are once again confined inside the cannula **60**.

In an eighth embodiment, shown in FIGS. 8C-D, the cannula **60** has a proximal section **88** and a distal section **90** separated by a circumferential gap **92**, as described in connection with the third embodiment (FIGS. 5D-F) and the fifth embodiment (FIGS. 6D-F). Unlike the third and fifth embodiments, in which the distal tips of the probes **16** atraumatically contact the wall **14**, in the eighth embodiment the distal tips of the probes **16** are attached to a hub **78** at the distal section **90** of the cannula **60**. Like the probes **16** of the seventh embodiment, the probes **16** of the eighth embodiment have side windows **82** at intermediate points for atraumatically contacting the arterial wall **14**. An actuator (not shown) is mechanically coupled to selectively apply tension to the probes **16**. When the probes **16** are under tension, they lie against the distal section **90** of the cannula **60**, as

shown in FIG. 8D. When probes 16 are relaxed, they spring radially outward, away from the distal section 90, enough so that the side windows 82 at the intermediate sections atraumatically contact the arterial wall 14.

In use, the cannula 60 is guided to a region of interest with the probes 16 placed under tension. The probes 16 are thus drawn against the cannula 60, as shown in FIG. 8B. Once at the region of interest, the tension is released, and the probes 16 spring radially outward, as shown in FIG. 8A, so that the side windows 82 atraumatically contact the wall 14. After data collection, the probes 16 are again placed under tension to draw them back against the cannula 60, as shown in FIG. 8B.

In the seventh and eighth embodiments, a particular probe 16 emerges from the cannula 60 at an exit point and re-attaches to the hub 78 at an anchor point. In a cylindrical coordinate system centered on the axis of the cannula 60, the exit point and the anchor point have different axial coordinates but the same angular coordinate. However, as FIGS. 8E and 8F illustrate, this need not be the case.

FIG. 8E shows a ninth embodiment in which a cannula 60 has a plurality of exit holes 96 and a corresponding plurality of entry holes 98. Each probe 16 exits the cannula 60 through an exit hole 96 and re-enters the cannula 60 through an entry hole 96 that is circumferentially offset from its corresponding exit hole. This results in the helical arrangement shown in FIG. 8E. The extent of the circumferential offset defines the pitch of the helix.

The distal ends of the probe 16 are attached to a hub 78 (not shown) inside the cannula 60. Each probe 16 has a side window 82 between the exit hole and the corresponding entry hole. A control wire 80 within the cannula 60 (not shown) deploys the probes 16, as shown, or retracts them so that they rest against the exterior of the cannula 60. A guide-wire 63 passing through the cannula 60 and exiting out the distal tip thereof enables the cannula 60 to be guided to a region of interest.

FIG. 8F shows a tenth embodiment in which a cannula 60 has a distal section 88 and a proximal section 90. The proximal and distal sections of the cannula 60 surround a

central shaft **100** having an exposed portion **102**. Probes **16** extend axially through a gap between the shaft and the cannula **60**. The probes **16** are anchored at their distal ends at circumferentially displaced anchor points on a hub **78** attached to the shaft **100**. The circumferential offset causes the helical configuration of the probes **16** in FIG. 8F. The extent of this circumferential offset defines a pitch of the helix.

An actuator (not shown) selectively applies tension to the probes **16**. When the probes **16** are under tension, they retract against the exposed portion **102** of the central shaft **100**. When the probes **16** are relaxed, they assume the configuration shown in FIG. 8F, in which they spring radially outward from the exposed portion **102** of the central shaft **100** so that their side windows **82** atraumatically contact the arterial wall **14**.

In the embodiments described thus far, the probes **16** and the cannula **60** have been separate structures. However, the probes **16** can also be integrated, or otherwise embedded in the cannula **60**. In this case, portions of the cannula **60** extend radially outward to contact the arterial wall **14**.

FIGS. 8G and 8H show an eleventh embodiment in a deployed and retracted state, respectively. The eleventh embodiment includes slots **104** cut into the wall of the cannula **60** enclosing an internal shaft **100**. Pairs of adjacent slots **104** define probe portions **16** of the cannula **60**. The probe portions **16** buckle outward when the distal tip of the cannula **60** is pulled proximally, as shown in FIG. 8G. When the distal tip of the cannula **60** is extended, the probe portions **16** lay flat against the shaft **100**, as shown in FIG. 8H.

Each probe portion **16** has a side window **82** for atraumatically contacting the wall **14** when the probe portion **16** is deployed. The side window **82** is in optical communication with an atraumatic coupler **24**. An optical fiber embedded within the wall of the cannula **60** provides an optical path to and from the atraumatic coupler **24**.

FIGS. 8I-J show a twelfth embodiment in a deployed and retracted state. The twelfth embodiment includes slots **104** cut into the wall of the cannula **60** enclosing an internal shaft **100**. Unlike the slots **104** in the eleventh embodiment, the slots **104** in the twelfth embodiment extend all the way to the distal tip of the cannula. Pairs of adjacent

slots **104** define probe portions **16** of the cannula **60**.

As shown in the cross-section of FIG. 8K, the cannula **60** includes radially-inward projections **106** forming a throat **110**. The shaft **100** has a bulbous portion **112** distal to the throat **110** and a straight portion **114** extending proximally through the throat **110** to join the bulbous portion **112**. The probe portions **16** are biased to rest against the bulbous portion **112** of the shaft **100**, as shown in FIG. 8I. When the shaft **100** is drawn proximally, the bulbous portion **112** wedges against the projections **106**. This forces the probe-portions **16** to pivot radially outward, as shown in FIG. 8J.

Each probe portion **16** has an atraumatic coupler **24** at its distal tip for atraumatically contacting the wall **14** when the probe portion **16** is deployed. An optical fiber embedded within the wall of the cannula **60** provides an optical path to and from the atraumatic coupler **24**.

OTHER EMBODIMENTS

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

CLAIMS

1. An apparatus for detecting vulnerable plaque within a lumen defined by an intraluminal wall, the apparatus comprising:
 - a probe having
 - an optical fiber extending therethrough, and
 - an atraumatic light-coupler in optical communication with the optical fiber, the coupler being configured to atraumatically contact the intraluminal wall;
 - a light source in optical communication with the fiber for illuminating the wall; and
 - a detector in optical communication with the fiber for detecting light from within the wall.
2. The apparatus of claim 1, wherein the probe further comprises a jacket enclosing the fiber.
3. The apparatus of claim 2, wherein the jacket comprises a coil-wire wound into a coil-wire jacket.
4. The apparatus of claim 3, wherein the jacket comprises a coil wire having a variable diameter.
5. The apparatus of claim 1, wherein the probe comprises a plurality of optical fibers.
6. The apparatus of claim 1, wherein the probe resiliently assumes a preferred shape.
7. The apparatus of claim 6, wherein the preferred shape comprises a bow.
8. The apparatus of claim 6, wherein the preferred shape comprises an arc.

9. The apparatus of claim 6, wherein the preferred shape comprises a portion of a catenary curve.
10. The apparatus of claim 1, wherein the atraumatic coupler is disposed at a distal tip of the probe.
11. The apparatus of claim 10, wherein the atraumatic coupler comprises a lens attached to the distal tip of the optical fiber.
12. The apparatus of claim 11, wherein the lens has a focal length that limits the divergence angle of a beam mode-matched to the optical fiber.
13. The apparatus of claim 12, wherein the lens has a focal length that limits the divergence angle to an angle less than about 20 degrees.
14. The apparatus of claim 12, wherein the lens comprises a collimating lens.
15. The apparatus of claim 10, wherein the atraumatic coupler comprises a divergence limiter attached to the distal tip of the optical fiber.
16. The apparatus of claim 15, wherein the divergence limiter comprises a thermally-expanded fiber core section of the optical fiber.
17. The apparatus of claim 10, wherein the atraumatic coupler is integral with the optical fiber.
18. The apparatus of claim 17, wherein the atraumatic coupler comprises a distal tip of the optical fiber.
19. The apparatus of claim 18, wherein the optical fiber has an acceptance angle smaller than about 20 degrees.
20. The apparatus of claim 1, wherein the atraumatic coupler is disposed along a side of the probe.

21. The apparatus of claim 20, wherein the atraumatic coupler comprises a window along a side of the probe.
22. The apparatus of claim 21, further comprising a diffraction grating in optical communication with the window.
23. The apparatus of claim 20, wherein the atraumatic coupler comprises:
 - a window along a side of the probe, and
 - a beam re-director providing optical communication between the window and a distal tip of the fiber.
24. The apparatus of claim 23, wherein the beam re-director comprises a prism.
25. The apparatus of claim 20, wherein the atraumatic optical coupler comprises:
 - a window along the side of the probe, and
 - a distal face of the optical fiber, the face being oriented to provide optical communication with the window.
26. The apparatus of claim 1, wherein the light source comprises a near infrared light source.
27. The apparatus of claim 1, further comprising a processor in data communication with the detector, the processor being configured to identify a vulnerable plaque on the basis of a signal provided by the detector.
28. The apparatus of claim 1, further comprising a cannula through which the probe passes.
29. The apparatus of claim 28, wherein the probe is integral with the cannula.

30. The apparatus of claim 28, wherein the optical fiber is embedded within the cannula.
31. The apparatus of claim 28, wherein the cannula comprises walls forming a channel through which the probe passes, the channel being conformal to the cannula.
32. The apparatus of claim 31, wherein the cannula has a tapered distal opening such that the channel has an opening facing a longitudinal axis of the cannula.
33. The apparatus of claim 31, wherein the cannula has a flared distal opening such that the channel has an opening facing away from a longitudinal axis of the cannula.
34. The apparatus of claim 1, further comprising a hub to which a distal end of the probe is attached.
35. The apparatus of claim 34, further comprising a cannula through which the hub and the probe pass.
36. The apparatus of claim 35, wherein the probe resiliently assumes a bow shape for contacting the intraluminal wall at a point of inflection thereof.
37. The apparatus of claim 36, wherein the coupler is disposed at the point of inflection.
38. The apparatus of claim 1, further comprising a spacer attached to the probe for maintaining a preferred relative position of the probe.
39. An apparatus for detecting vulnerable plaque within a lumen defined by an intraluminal wall, the apparatus comprising:
 - a cannula having a longitudinal axis;

a plurality of probes extending through the cannula, each probe having

an optical fiber extending therethrough, and

an atraumatic light-coupler in optical communication with the optical fiber, the coupler being configured to atraumatically contact the intraluminal wall.

40. The apparatus of claim 39, further comprising a spacer ring attached to each of the probes for maintaining the positions of the probes relative to each other.
41. The apparatus of claim 39, further comprising a hub attached to a distal end of each of the probes.
42. The apparatus of claim 41, wherein the distal end of the probe is attached to the hub at an anchor point that is circumferentially offset from a proximal portion of the probe.
43. The apparatus of claim 41, further comprising a spacer ring attached to each of the probes for maintaining the positions of the probes relative to each other.
44. The apparatus of claim 41, wherein each of the probes resiliently assumes a bow shape having a point of inflection between the hub and the cannula.
45. The apparatus of claim 39, wherein each of the probes resiliently assumes a desired shape.
46. The apparatus of claim 39, wherein the atraumatic coupler comprises means for providing optical communication between the optical fiber and the intraluminal wall.

47. The apparatus of claim 39, wherein at least one of the plurality of probes is integral with the cannula.
48. The apparatus of claim 39, wherein the optical fiber is embedded within the cannula.
49. A method of detecting vulnerable plaque within an intraluminal wall, the method comprising:
- placing an atraumatic light coupler in contact with the intraluminal wall;
 - passing light through the intraluminal wall by way of the atraumatic light coupler;
 - receiving light from within the intraluminal wall by way of the atraumatic coupler; and
 - providing the received light to a processor for analysis to identify the presence of a vulnerable plaque.
50. The method of claim 49, wherein placing an atraumatic light coupler in contact with the intraluminal wall comprises placing a distal end of a probe in contact with the intraluminal wall.
51. The method of claim 49, wherein placing an atraumatic light coupler in contact with the intraluminal wall comprises placing a side of a probe in contact with the intraluminal wall.
52. An apparatus for detecting vulnerable plaque within a lumen defined by an intraluminal wall, the apparatus comprising:
- a probe having
 - an optical fiber extending therethrough, and

means for atraumatically contacting the intraluminal wall,
the contacting means including means for providing
optical communication with the intraluminal wall;

a light source in optical communication with the fiber for
illuminating the wall; and

a detector in optical communication with the fiber for detecting
light from within the wall.

53. The apparatus of claim 52, wherein the means for atraumatically contacting the intraluminal wall comprises a rounded surface at a distal tip of the probe.
54. The apparatus of claim 53, wherein the rounded surface comprises a surface of a lens attached to the fiber.
55. The apparatus of claim 54, wherein the means for providing optical communication comprises the lens.
56. The apparatus of claim 53, wherein the rounded surface comprises a surface of the fiber.
57. The apparatus of claim 49, wherein the means for providing optical communication comprises the fiber.
58. The apparatus of claim 52, wherein the means for atraumatically contacting the intraluminal wall comprises a side-window along a side of the probe.
59. The apparatus of claim 58, wherein the means for providing optical communication comprises a reflective surface in optical communication with the side-window and with a face of the fiber.

60. The apparatus of claim 58, wherein the means for providing optical communication comprises an angled face of the fiber.
61. The apparatus of claim 58, wherein the means for providing optical communication comprises a diffraction grating in optical communication with the side-window and with the fiber.

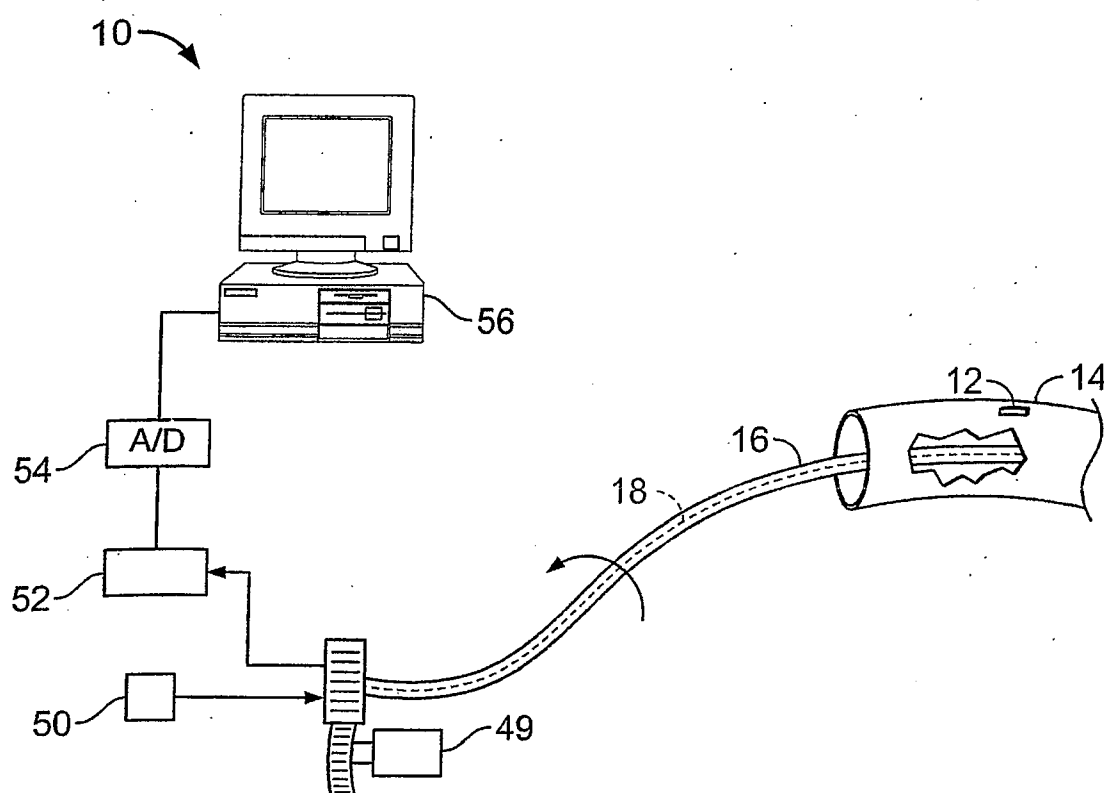


FIG. 1

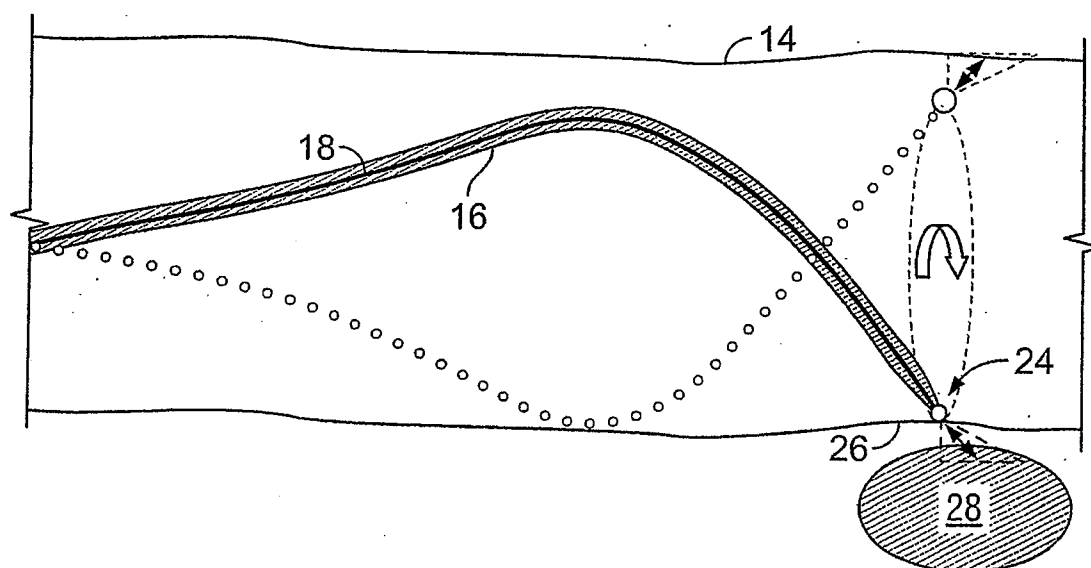


FIG. 2

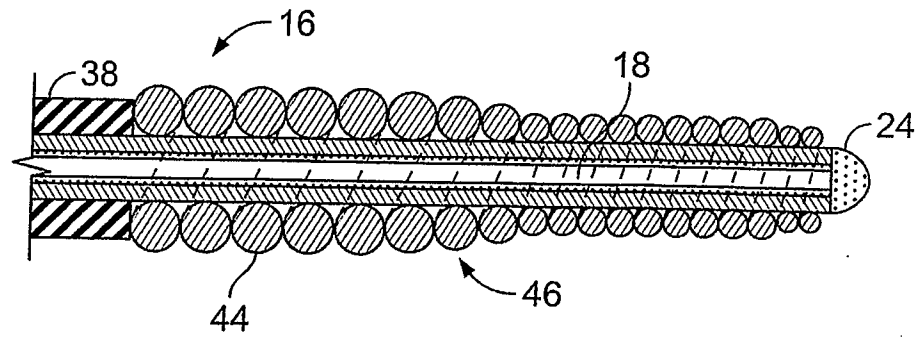


FIG. 3

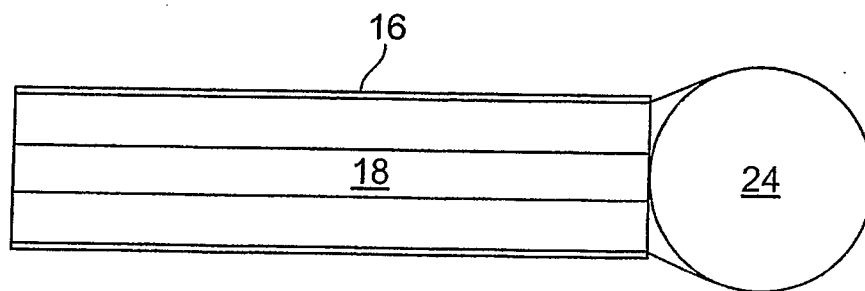


FIG. 4A

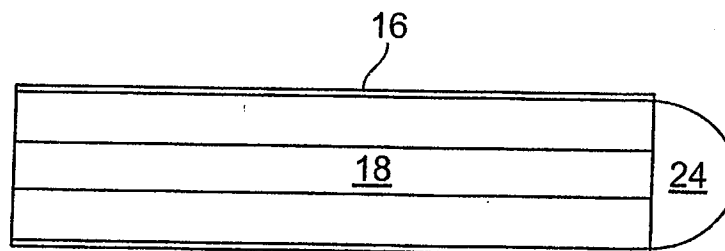


FIG. 4B

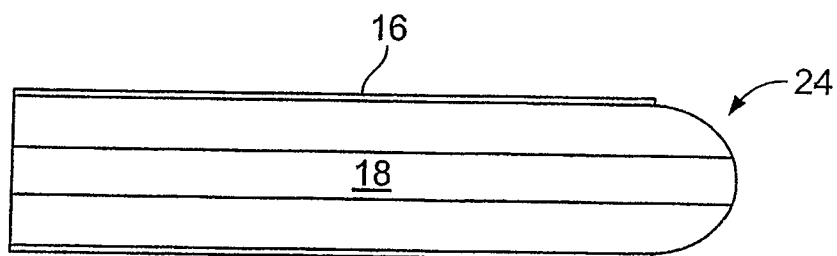


FIG. 4C

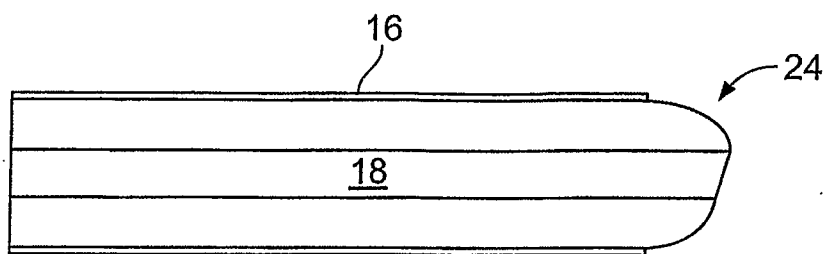


FIG. 4D

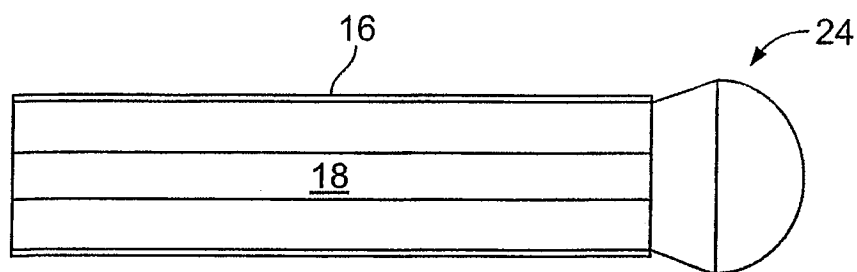


FIG. 4E

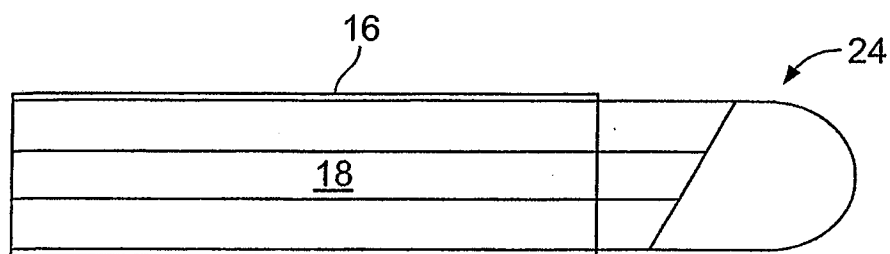


FIG. 4F

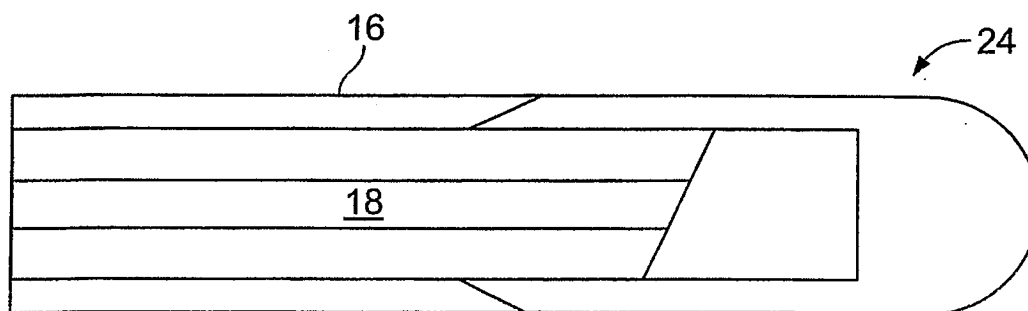


FIG. 4G

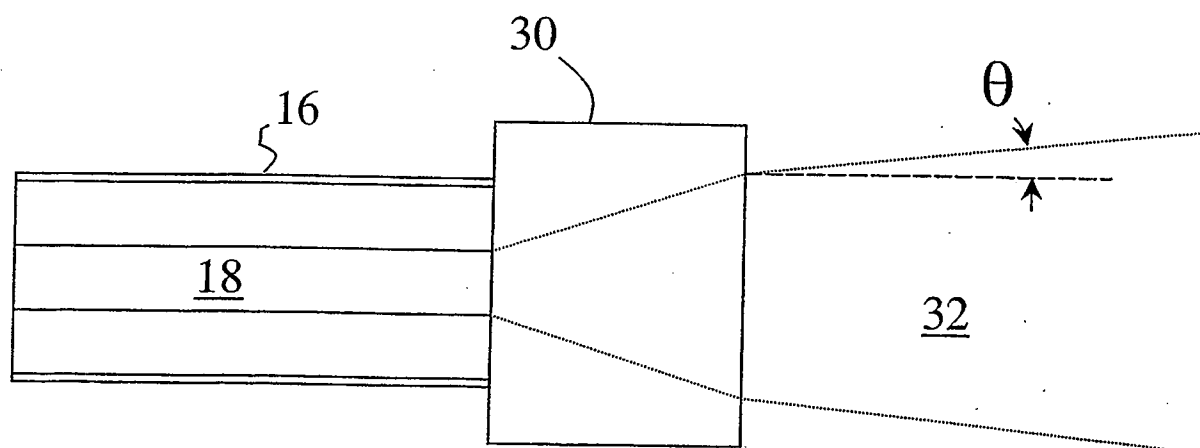


FIG. 4H

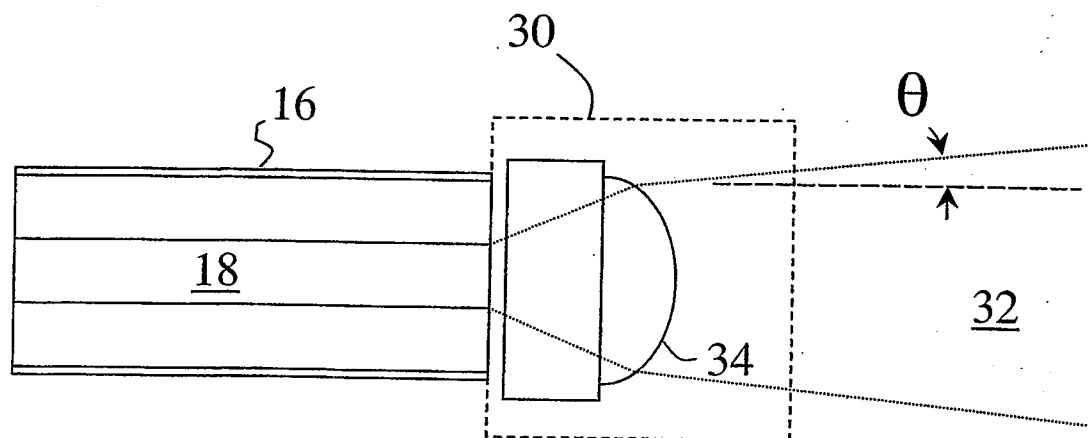


FIG. 4I

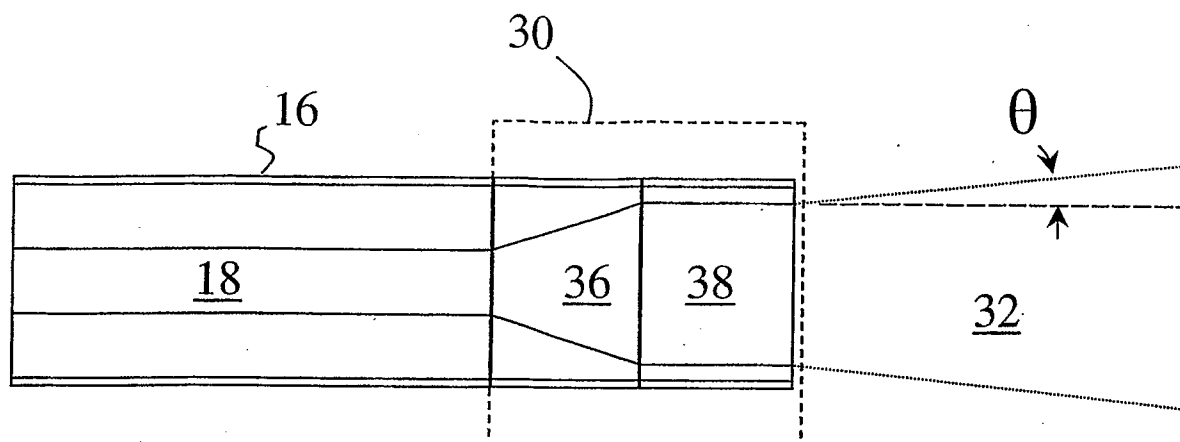


FIG. 4J

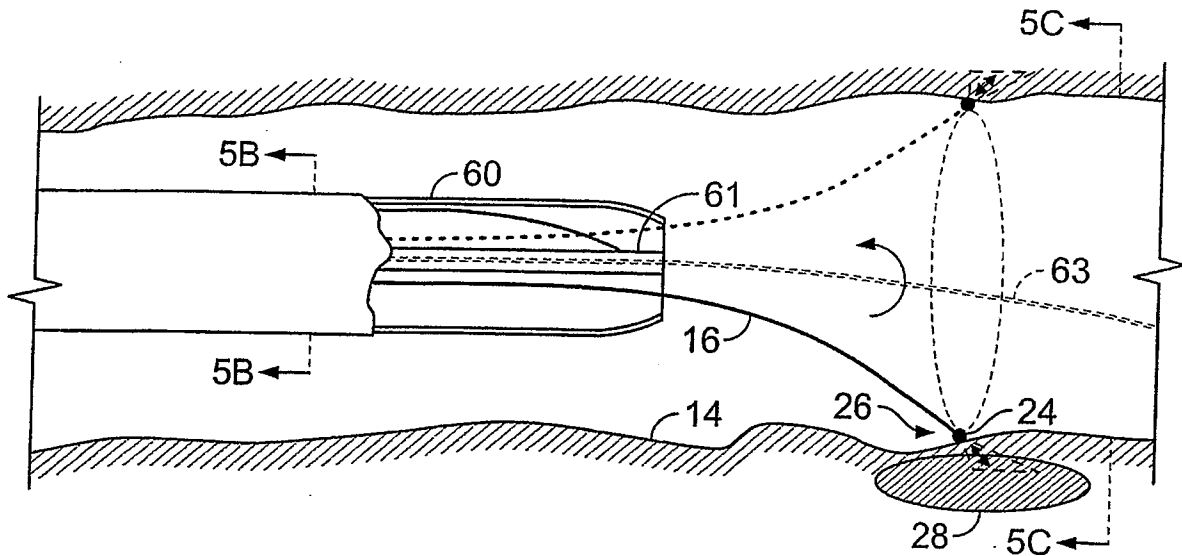


FIG. 5A

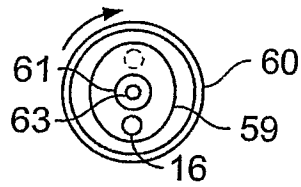


FIG. 5B

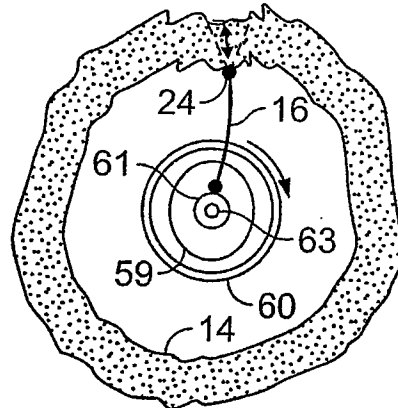


FIG. 5C

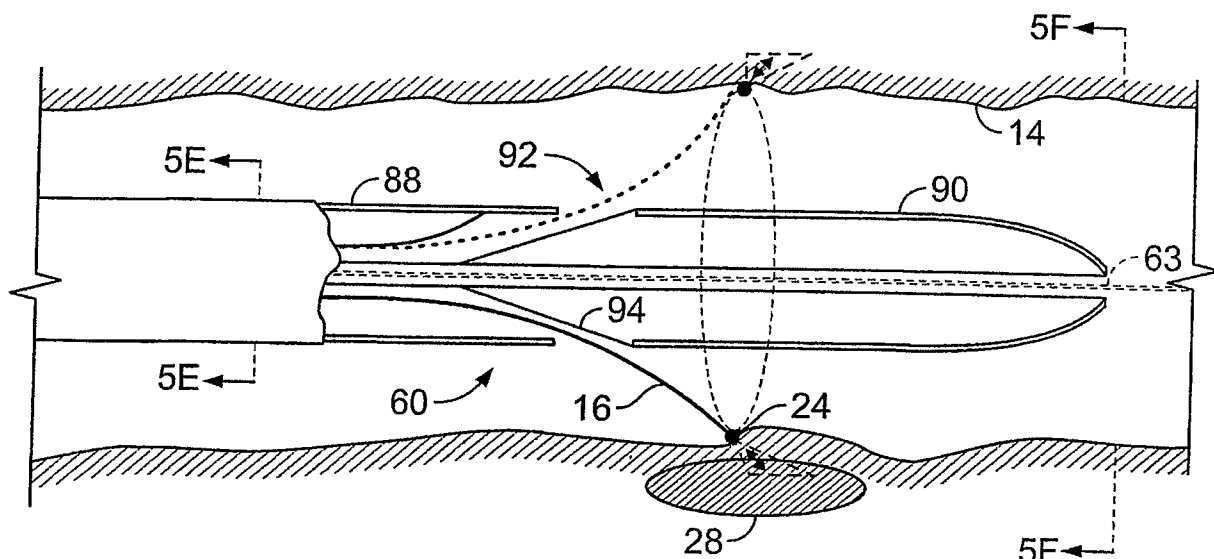


FIG. 5D

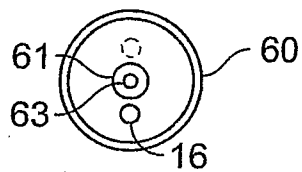


FIG. 5E

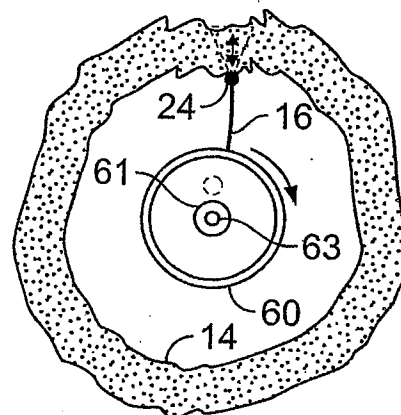


FIG. 5F

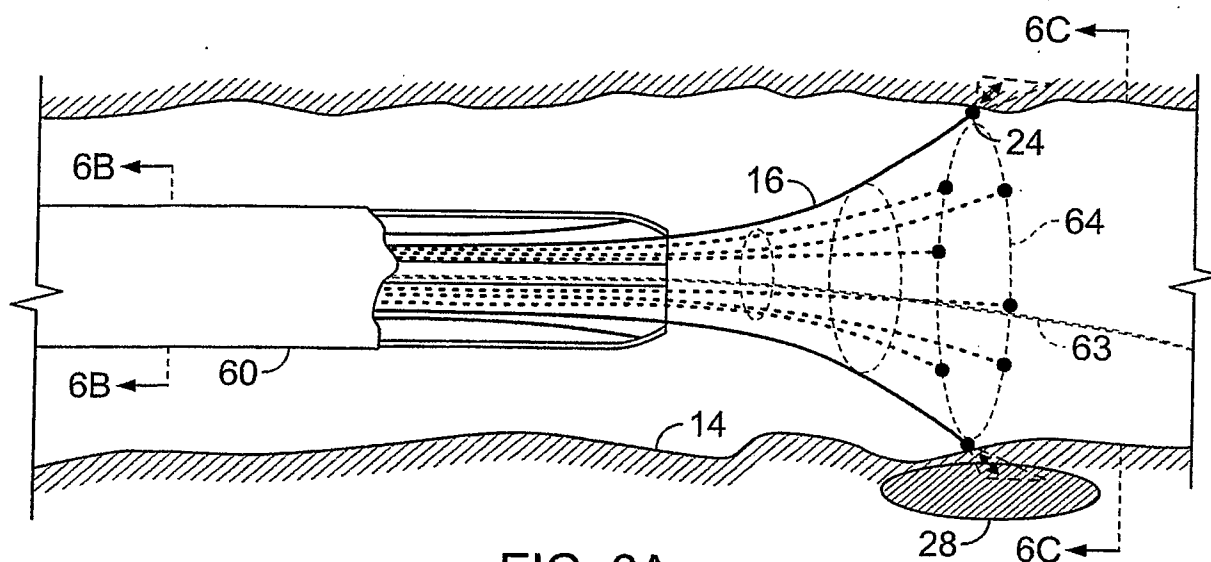


FIG. 6A

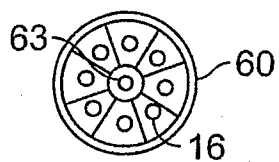


FIG. 6B

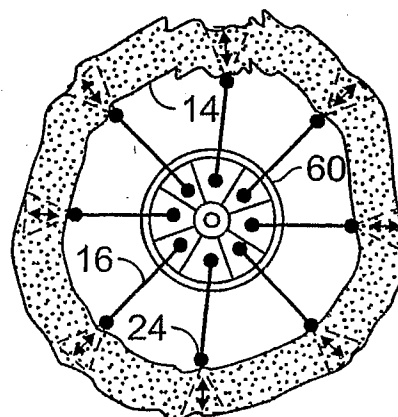


FIG. 6C

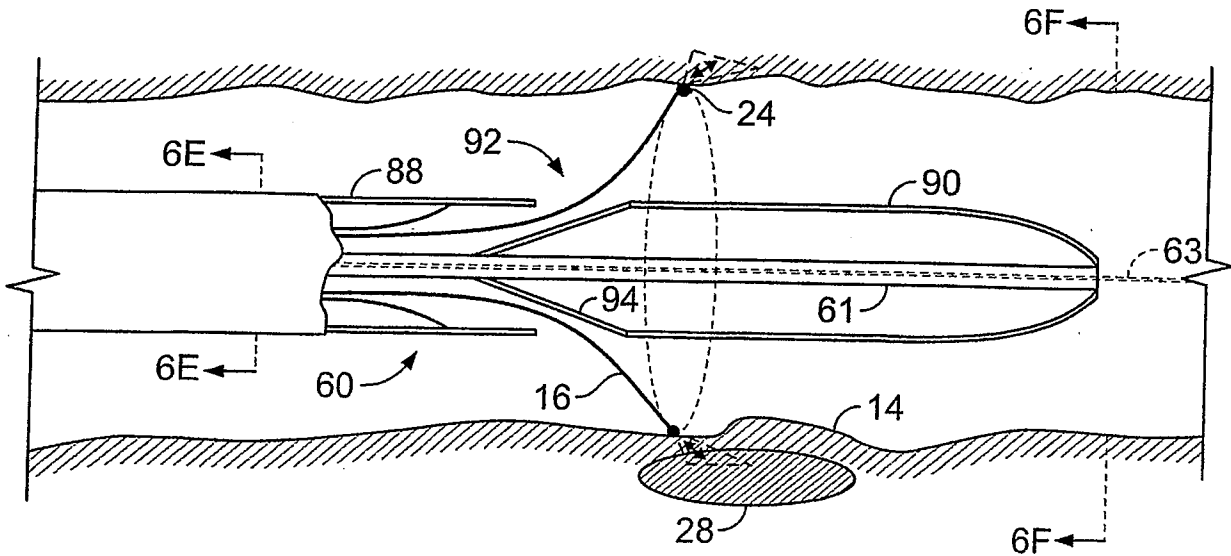


FIG. 6D

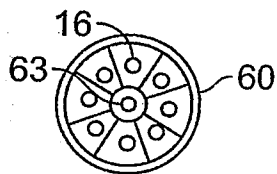


FIG. 6E

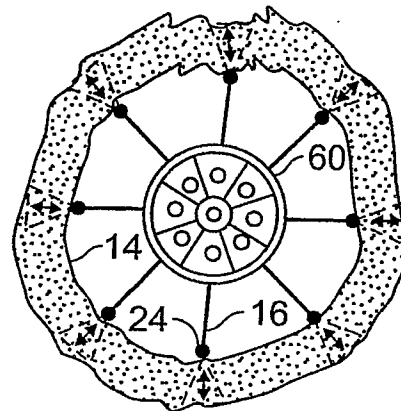


FIG. 6F

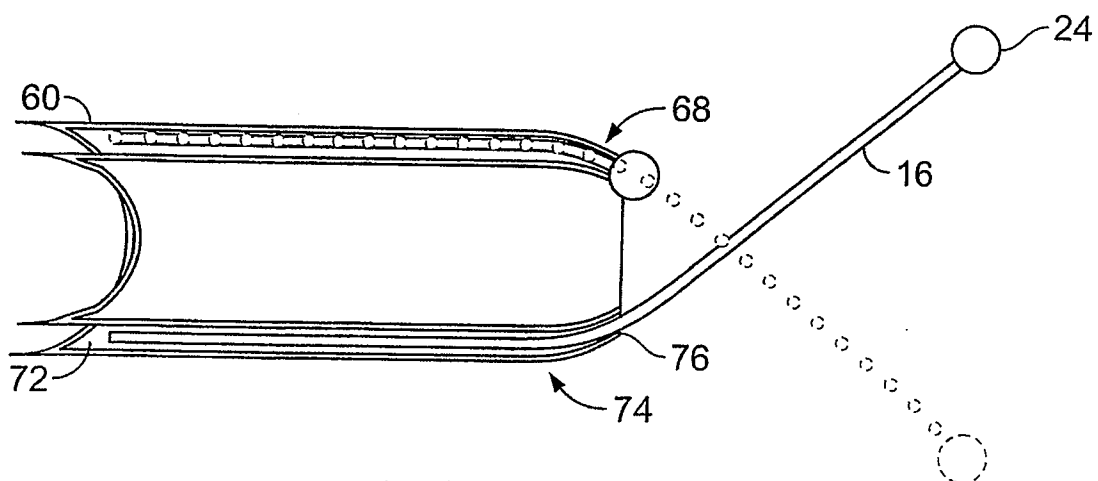


FIG. 7A

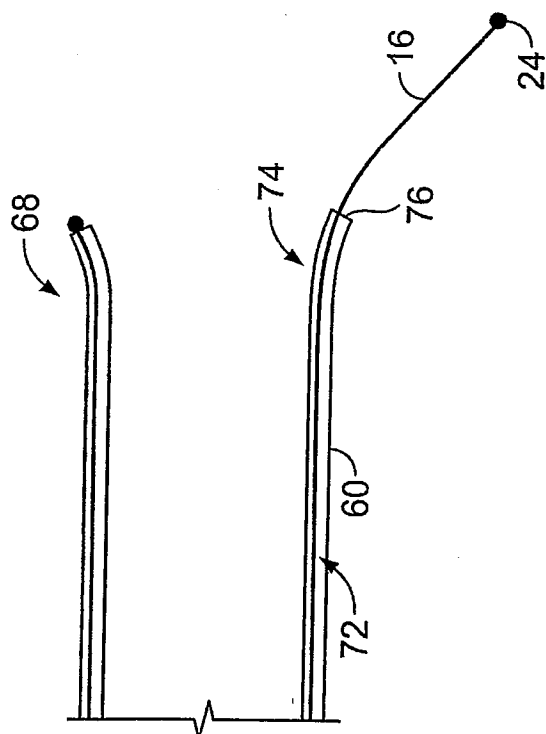


FIG. 7B

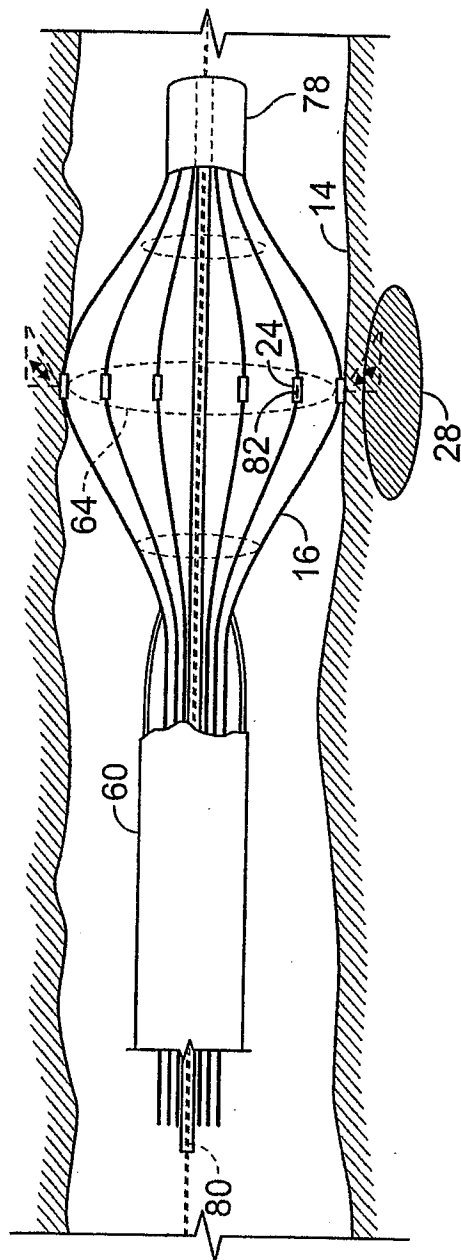


FIG. 8A

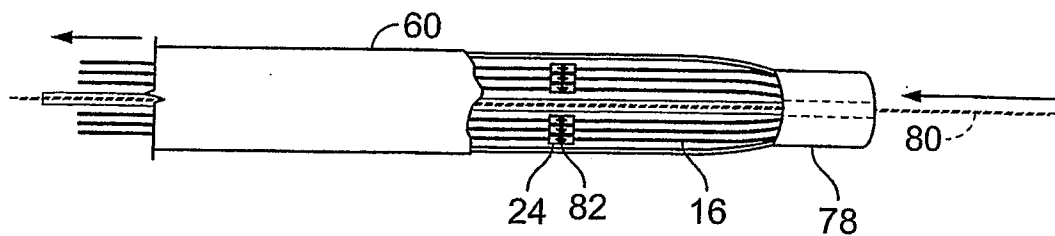


FIG. 8B

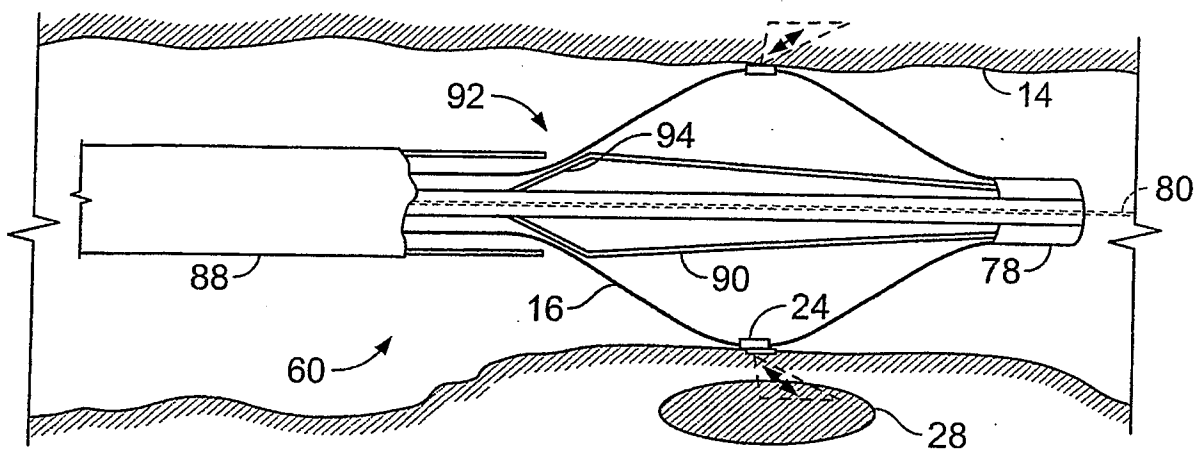


FIG. 8C

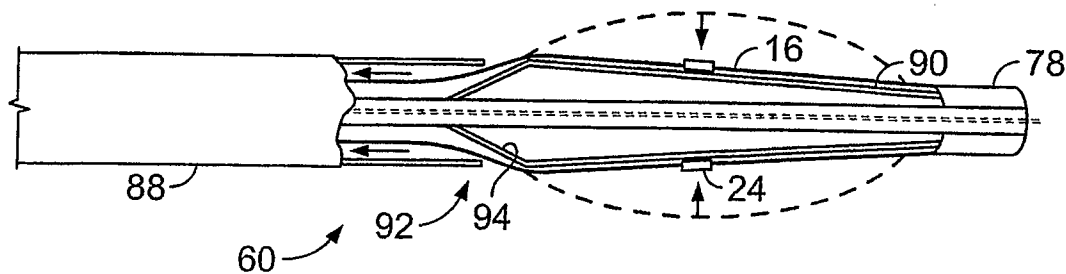


FIG. 8D

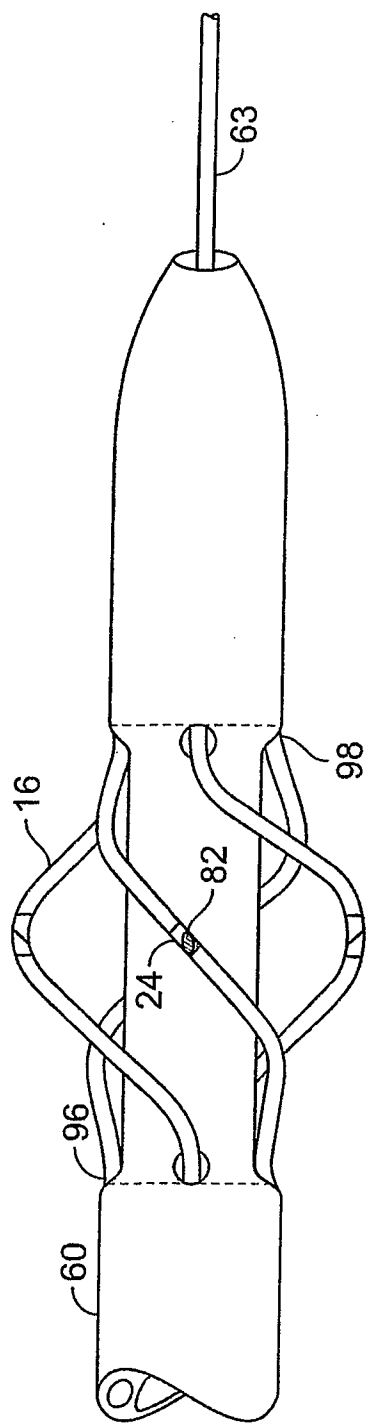


FIG. 8E

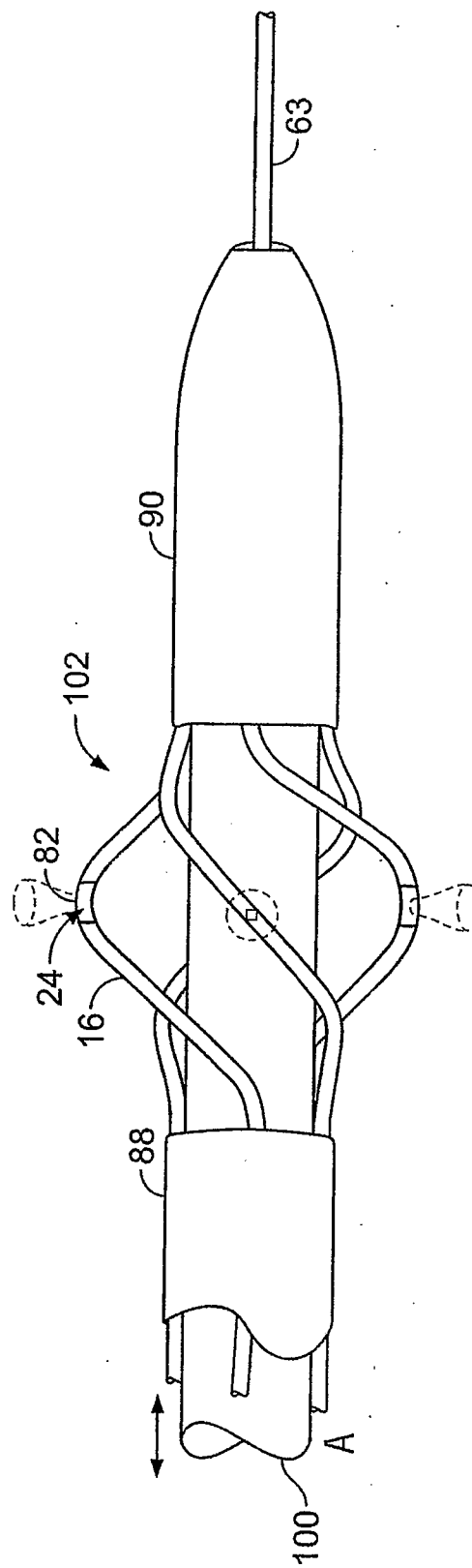


FIG. 8F

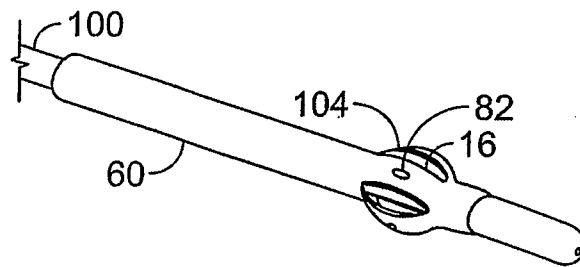


FIG. 8G

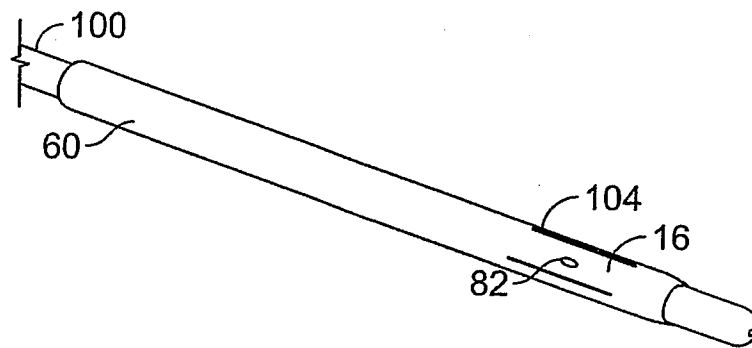


FIG. 8H

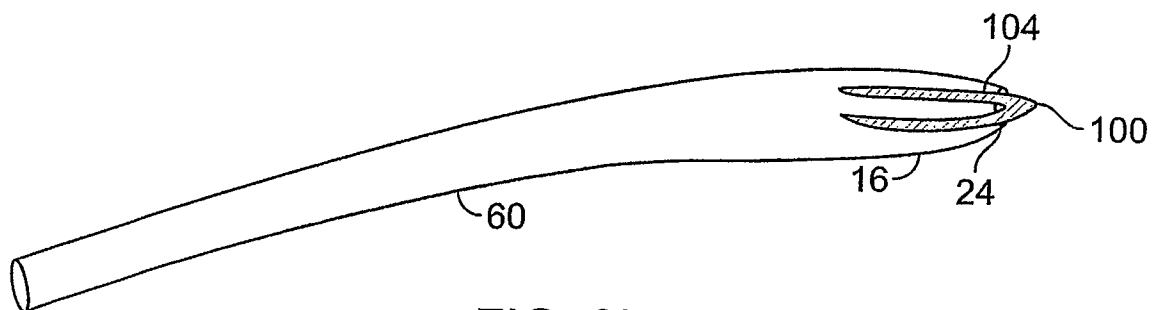


FIG. 8I

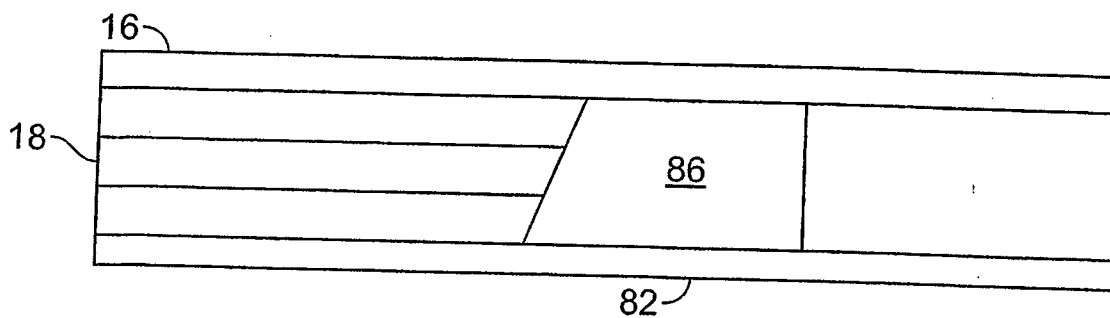


FIG. 9A

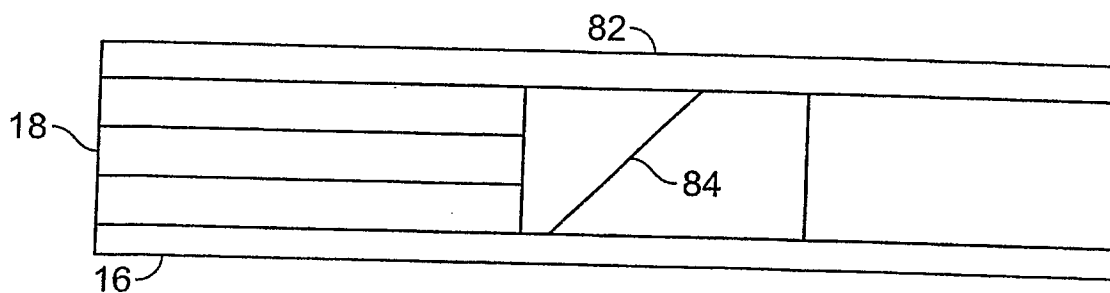


FIG. 9B

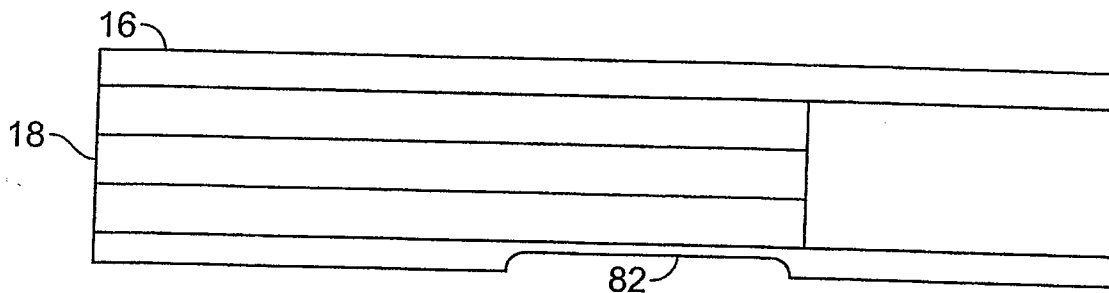


FIG. 9C

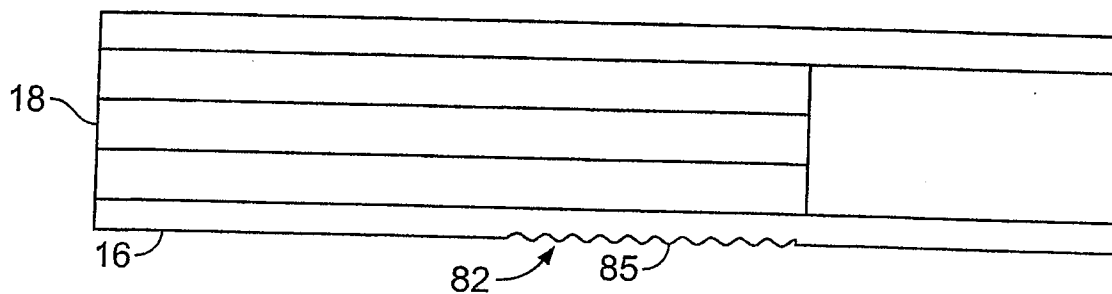


FIG. 9D

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/19883

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/00

US CL : 600/478

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/114, 104, 473, 476, 478; 604/22, 164.01, 164.02; 385/12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,485,413 B1 (BOPPART et al) 26 November 2002 (26.11.2002), see Figure 18 and col. 28, line 51-col. 30, line 56.	1-61

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

30 September 2004 (30.09.2004)

Date of mailing of the international search report

19 OCT 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Eleni Mantis Mercader

Telephone No. 703 308-0858

Sheila H. Vandy
Patent Specialist
Tech. Center 3700